DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

September 25, 2001

WARNING LETTER
SJN-01-22

CERTIFIED MAIL
Return Receipt Requested

Mrs. Gregory Schuster
Owner
Schuster Services & Blue Mountain Water
P.O. Box 948
St. Croix, USVI 00821

Dear Mr. Schuster:

On 5/29-30/01, the Food and Drug Administration (FDA) conducted an inspection of your water bottling plant located at 18 Estate Pearl, Saint Croix, USVI 00850. The inspectional findings and product label review revealed that your product is adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(a)(1) of the Federal Food, drug and Cosmetic Act; and in violation of Title 21, Code of Federal Regulations, Parts 129 (Processing and Bottling of Bottled Drinking Water), 165.110 (Standard of Identity for Bottled Water) and 101 (Food Labeling) as follows:

1. Your "Purified Drinking Water" filled in 5-gallon containers and in 24 fl. oz. bottles is misbranded within the meaning of the act. The product label for "ST. CROIX'S OWN PURIFIED DRINKING WATER" and "VIRGIN PURE" states these products are purified by Reverse Osmosis (RO) and Ultraviolate Rays (UV). However, the inspection revealed that the RO and UV equipment have been out of order for more than 3 months but that you continue labeling these products as purified by mean of a RO and UV process. [21 CFR 165.110 (a)(2)(iv)]

2. The 5-gallon multi-service containers are not sanitized in an enclosed room as required to avoid any post-sanitizing contamination of the containers before they enter the bottling room. Instead they are washed and sanitized in an open area in which they are exposed to becoming contaminated. There is also no assurance that the sanitizing solution preparation is equivalent in bacteriacidal action to a 2 minute exposure of 50 ppm of available chlorine. [21 CFR 129.20 (d) and 129.80(d]

3. Failure to maintain records of the government agencies approving the source of water. [21 CFR 129.80 (3)]

4. Your bottled water is not identified with a production code as required. Each unit packaged from a batch or segment of a continuous production run of bottled drinking water is required to be identified with a production code. [21 CFR 129.80 (e)]

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Carmelo Rosa, Acting Compliance Officer.

Sincerely,

Mildred R. Barber

Mildred R. Barber
District Director